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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,966

11/12/2003

Charles H. Pugsley

81614A

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22852

7590

03/06/2008

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

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03/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/712,966	<b>Applicant(s)</b> PUGSLEY ET AL.	
	<b>Examiner</b> Julian W. Woo	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-28 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-21 is/are allowed.
- 6) ☒ Claim(s) 1-4 and 28 is/are rejected.
- 7) ☒ Claim(s) 5-7 and 22-27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-4 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (6,620,194) in view of Yang et al. (6,258,121). Ding et al. discloses the invention substantially as claimed. Ding et al. disclose, at least in figure 9 and in col. 3, lines 1-20; col. 4, lines 5-13; and col. 13, line 43 to col. 14, line 19 and col. 15, lines 1-4, a biocompatible fastener (101 and 106 combined) comprising a pair of members (101 and 106) matingly engageable with one another (via 102) and configured to fasten together two or more biological materials (e.g., blood vessels and/or grafts), where one the members comprises an outer coating (102) coated over a non-bioabsorbable (metal) material, where the outer coating comprises a first bioabsorbable material, where the inner core comprises the non-bioabsorbable material (metal), where after the

pair of members are matingly engaged with one another, degradation of the outer coating causes the pair of members to disengage from one another, and where only one of the members (101) comprises an outer coating coated over the inner core. However, Ding et al. do not specifically disclose that the first bioabsorbable material has a first degradation rate that is slower than a second degradation rate of a second bioabsorbable material of an inner core (polymeric). Yang et al. teach, at least in col. 3, line 65 to col. 4, line 66 and col. 5, lines 38-65; an outer coating of a first bioabsorbable material (e.g., PLA /PEO) coated over an inner core (10 or 110) formed of non-bioabsorbable material (e.g., "metallic materials") or a second bioabsorbable material (e.g., PLA/PCL), where the degradation rate of the first absorbable material is faster than the degradation rate of the second bioabsorbable material. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the inner core of the device of Ding et al., in view of Yang et al., so that it is formed a second bioabsorbable material having a slower degradation rate than the first bioabsorbable material. Such an inner core formed of a bioabsorbable material would allow the scaffolding of a blood vessel, so that a therapeutic member or material can be first released into the diseased tissue before the patient's body absorbs both the inner core and outer coating.

***Allowable Subject Matter***

3. Claims 5-7 and 22-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a biocompatible fastener including, inter alia, a male member with a head and a female member with a bore and a flange, where at least one of the members includes an outer coating coated over an inner core, the outer coating comprising a first bioabsorbable material, the inner core comprising one of second bioabsorbable material and a non-bioabsorbable material, where after the members have been matingly engaged with one another, degradation of the outer coating over the inner core causes the members to disengage from one another.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

5. Claims 9-21 are allowed.

6. The following is an examiner's statement of reasons for allowance: The terminal disclaimer of June 7, 2007 overcomes the double patenting rejections in the Office action of March 2, 2007.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Response to Amendment***

7. Applicant's arguments filed on November 30, 2007 have been fully considered but they are not persuasive. That is, Ding and Yang indeed disclose fasteners that are stents. A stent is a fastener in that it is joined to and supports blood vessels and/or grafts, or it joins portions of blood vessels and/or grafts together. Moreover, the recitation that an element is "configured to fasten together two or more biological materials" is not a positive limitation but only requires the ability to so perform. It does not necessarily constitute a limitation in a patentable sense. In other words, a stent is capable of fastening together two or more biological materials. However, assuming arguendo that the stents of Ding and Yang are not fasteners, Ding discloses, in col. 3, lines 19-29, other coated devices that can be deemed fasteners (e.g., cardiovascular sutures).

Finally, the Examiner agrees with the Applicant that Ding teaches the advantages of metal stents over polymeric stents. However, Ding does not exclude or deny the use of polymeric stents in Ding's invention (See col. 3, lines 16-20 and col. 4, lines 5-13). In other words, Ding does not teach away the claimed invention, and Ding in view of Yang teaches a first bioabsorbable material having a first degradation rate that is slower than a second degradation rate of a second bioabsorbable material of a polymeric inner core (stent).

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/  
Primary Examiner, Art Unit 3773

February 28, 2008